In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 19-1217V

(to be published)

LARRY BULMAN, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Dated: August 16, 2023

David John Carney, Green & Schafle LLC, Philadelphia, PA, for Petitioner.

Claudia Barnes Gangi, U.S. Department of Justice, Washington, DC, for Respondent.

ENTITLEMENT DECISION[1]

On August 15, 2019, Larry Bulman filed a petition seeking compensation under the National Vaccine Injury Compensation Program ("Vaccine Program").[2] Petitioner alleges he suffered a left Shoulder Injury Related to Vaccine Administration ("SIRVA") following receipt of an influenza ("flu") vaccine on September 25, 2018. Petition (ECF No. 1) ("Pet.") at 1. The matter was originally assigned to the Special Processing Unit ("SPU"), but it was determined that Petitioner could not preponderantly establish that onset of his pain had occurred within 48 hours of vaccination, thus not satisfying a SIRVA Table claim element—and preventing recovery on that basis. *Bulman v. Sec'y of Health & Hum. Servs.*, No. 19-1217V, 2021 WL 4165349, at *2–3 (Fed. Cl. Spec. Mstr. Aug. 12, 2021) (the "Finding of Fact").

[1] Under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public in its present form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) ("Vaccine Act" or "the Act"). Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

However, I also found that the claim might still be successful if the causation-in-fact standards for entitlement could be met, and therefore the matter was transferred out of SPU and to my individual docket. After expert input was obtained, I proposed that the underlying issue of entitlement be decided on the record, and the parties have offered briefs in support of their respective positions. Petitioner's Motion, dated December 9, 2022 (ECF No. 38) ("Mot."); Respondent's Opposition, dated February 10, 2023 (ECF No. 40) ("Opp."); Petitioner's Reply, dated March 3, 2023 (ECF No. 41) ("Reply").

Now, after review of the medical records and briefs, I deny entitlement. It has not been preponderantly established that a SIRVA can likely occur if onset begins several days to more than a week post-vaccination, and Petitioner's history (as explained by the experts) does not permit me to conclude the flu vaccine was more than temporally related to his injury (however it is characterized).

I. Factual Background

Some of the factual summary was obtained from the fact determinations made prior to the claim's transfer out of SPU, based upon a complete review of the medical records, affidavits/witness statements, and Respondent's Rule 4(c) Report. Finding of Fact at *2–3. These findings stand as "law of the case"—and I note that no additional records or other, non-expert evidence has since been filed.

- Petitioner (who was 76 years old at the time) received a flu vaccine in his left arm on September 25, 2018. Ex 1 at 4–5.

- On December 26, 2018 (three months post-vaccination), Petitioner presented for an appointment with Dr. Prakash Bandari, an internist, with complaints of low back pain. Ex 3 at 98. Petitioner did not report any shoulder pain at this time, however, and a musculoskeletal examination revealed normal findings. *Id*. at 100. In fact, it was noted upon physical examination that he was able to move all four extremities. *Id.* Petitioner was also not then diagnosed with any shoulder-related condition. *Id*. at 100–01.

- One month later, on January 22, 2019, Petitioner returned to Dr. Bandari. Ex 3 at 93. He now reported "left shoulder pain x 4 months." *Id*. Petitioner further stated (somewhat incorrectly) that "he was given [a] flu shot in October and since then he had pain in shoulder." *Id*. Physical examination ("PE") by Dr. Bandari revealed restricted range of motion in the left shoulder, and Petitioner was diagnosed with rotator cuff tendonitis. *Id*. at 95–96.

- An X-ray of Petitioner's left shoulder was performed on January 29, 2019, and it showed a 4mm calcification adjacent to the humeral head, consistent with calcific tendinitis. Ex 3 at 684. The impression provided was calcific tendinitis. *Id.*

- On April 2, 2019, Petitioner presented for a follow-up appointment with Dr. Vikas Desai, his cardiologist.[3] Ex 3 at 7. He did not report shoulder pain at this visit. *Id*.

- Two months later, on June 11, 2019, Petitioner returned to Dr. Bandari, and he again reported left shoulder pain. Ex 4 at 10. There is no reference to the onset of Petitioner's pain in the records from this visit. *Id*. at 10–14. PE again revealed restricted range of motion. *Id*. at 12.

- In his affidavit, Petitioner avers that "immediately after receiving the flu shot, there was pain, discomfort and soreness in my left shoulder that was unusual" compared with his experience receiving flu vaccines for the prior eight years. Ex 2 at 2.

- Petitioner has further maintained that "[o]ver the next several days, the pain never subsided and in fact, the pain increased to the point where it began to affect all types of movement with [his] shoulder." Ex 2 at 2. He also stated that "[b]y September 27, 2018, [he] had ongoing severe pain in [his] left shoulder that [he] knew could not be normal post vaccine soreness" and that "[i]n the weeks that followed the flu shot, [his] left shoulder pain never improved." *Id*.

- In his affidavit, Petitioner stated that he experienced "sharp and shooting pains into [his] shoulder" when "reaching for objects, pushing doors open, turning the steering wheel, sleeping on [his] left side, cooking, cleaning, and getting dressed." Ex 2 at 2–3.

- In a supplemental affidavit, Petitioner stated that despite the fact that his shoulder pain began immediately after vaccination, he "had a previously scheduled appointment with Dr. Bandari on December 26, 2018," so he "decided to wait until that appointment to mention [his] shoulder pain." Ex 7 at 2.

- Petitioner alleges that the pain, discomfort, and decreased range of motion "persisted and never improved" from September 25, 2018 until December 26, 2018, the date of his visit with Dr. Bandari. Ex 2 at 3. In his affidavit, Petitioner avers that he reported his shoulder pain and other symptoms to Dr. Bandari at this visit, but he was "instructed . . . to make another appointment specifically for [his] left shoulder pain." *Id*.

[3] Petitioner has a longstanding history of congestive heart failure/cardiomyopathy and paroxysmal atrial fibrillation. *See, e.g.,* Ex 3 at 7; Ex 5 at 4.

- The Finding of Fact concluded that Table onset for a SIRVA claim could not be established, but that the record as it existed did seem to support other elements of such a claim. Finding of Fact at 7–8.

II. Expert Reports

A. *Petitioner's Expert – Naveed Mayer Natanzi, D.O.*

Dr. Natanzi, a board-certified specialist in physical medicine and rehabilitation, prepared two written reports for Petitioner in support of the contention that the flu vaccine can cause SIRVA, and that it did so in this case within the medically acceptable timeframe. Report, dated January 3, 2021, filed as Ex. P8 (ECF No. 30-1) ("Natanzi First Rep."); Report, dated February 16, 2022, filed as Ex. P11 (ECF No. 33-1) ("Natanzi Second Rep.").

Dr. Natanzi received a Bachelor of Arts in Biological Studies at the University of California, Santa Barbara in 2007, and attended medical school at Western University of Health Sciences, where he received a Doctor of Osteopathy in June 2012. *Curriculum Vitae,* filed as Ex. P10 on January 3, 2022 (ECF No. 30-2) ("Natanzi CV") at 2. Dr. Natanzi completed an internship at Downey Regional Medical Center from 2012-2013, then completed his residency in physical medicine and rehabilitation at the University of California, Irvine from 2013-2016. Natanzi CV at 1–2. Dr. Natanzi completed a fellowship at the Bodor Clinic in Napa, California from January 2017-August 2017. *Id.* at 1. From 2017-2018, Dr. Natanzi worked at the Pasadena Rehab Institute as an attending physician specializing in interventional pain management. *Id*. In November 2017, Dr. Natanzi founded the Regenerative Sports and Spine Institute, and since April 2018, Dr. Natanzi has been a staff physician at the VA Long Beach Healthcare System. *Id.*; Natanzi First Rep. at 1. Dr. Natanzi is board certified by the American Academy of Physical Medicine and Rehabilitation and is board-eligible by the American Board of Pain Management. Natanzi CV at 1; Natanzi First Rep. at 1.

First Report

After a summary of the medical records, Dr. Natanzi began with an overview of SIRVA injuries and the criteria for their diagnosis. Natanzi Rep. at 1–5, 8. In so doing, he summarized the Table elements. *Id.* at 8; Section 14(c)(10). SIRVA injuries occur, he explained, when there is an inadvertent overpenetration of the vaccination needle resulting in subacromial bursa and/or rotator cuff penetration. Natanzi First Rep. at 7. The vaccine interacts with naturally-occurring antibodies from a prior vaccination, resulting in an exaggerated, robust, and prolonged inflammatory response, which creates inflammation of the rotator cuff tendons and/or bursa causing pain. *Id*.

In Dr. Natanzi's opinion, Petitioner's injury clearly was consistent with the Table SIRVA element specific to the provided definition. Natanzi Rep. at 8–9; S. Atanasoff et al., *Shoulder Injury*

Related to Vaccine Administration (SIRVA), 28 Vaccine 8049, 8050 (2010), filed as Ex. 9(d) (ECF No. 31-4) (discussing the clinical characteristics of 13 patients with SIRVAs) ("Atanasoff"); M. Barnes et al., *"A "Needling" Problem: Shoulder Injury Related to Vaccine Administration*, 25 J. Am. Bd. Family Med. 919, 921 (2012), filed as Ex. 9(e) (ECF No. 31-5) (describing one SIRVA case) ("Barnes"). Such literature all consistently set forth certain symptomatic criteria—shoulder pain, decreased range of motion, adhesive capsulitis, rotator cuff tearing/tendinopathy, subacromial bursitis, clinical signs of impingement, weakness, and bicipital tendinitis—consistent with what Petitioner had experienced. Natanzi Rep. at 8. And his lack of a history of shoulder pain *prior* to vaccination supported the diagnosis (especially in comparison to what he experienced thereafter). Natanzi First Rep. at 7, 9; Ex 2 at 2–3; Ex. 3 at 93; Ex. 4 at 10; Ex. 7 at 2.

Dr. Natanzi acknowledged that the record contained limited discussion of shoulder pain *overall*, no musculoskeletal exam was performed on Petitioner's shoulder, and there was no MRI imaging available either. Natanzi First Rep. at 7. The X-ray obtained in January 2019 revealed calcific tendinopathy, but Dr. Natanzi deemed this to be a chronic, age-related finding separate from the reported post-vaccination pain, and in any event X-rays are not useful in the diagnosis of acute inflammatory tendinopathy or bursitis (which can be indicia for SIRVA). *Id.*

Dr. Natanzi then addressed the issue of onset. Natanzi First Rep. at 6. In his view, most people are unaware that a vaccine can cause significant shoulder dysfunction, and thus they do not usually attribute symptoms they might experience post-vaccination to a vaccine. Natanzi First Rep. at 6. Accordingly, many patients (like Petitioner) wait to see if the injuries they are experiencing might self-resolve before seeking actual professional treatment. Natanzi First Rep. at 6; J. Taber et al., *Why Do People Avoid Medical Care? A Qualitative Study Using National Data*, 30 J. General Internal Med. 290, 290–91 (2015), filed as Ex. 9(a) (ECF No. 31-1) (exploring the question of why patients avoid medical care and finding that 12.2 percent of patients experienced a low perceived need to seek medical care, often because they believed symptoms would self-improve over time).

Mr. Bulman's record revealed a complex medical history with several comorbidities (e.g., cardiomyopathy, atrial fibrillation and heart failure, pulmonary hypertension, and deep vein thrombosis) that required specialized treatments. In the context of addressing such unrelated concerns, Dr. Natanzi maintained, it was unlikely that every other possible concern a patient might have would be discussed. Natanzi First Rep. at 6. And in fact, the Petitioner had noted he was unable to discuss his new shoulder pain issue with Dr. Bandari on December 26, 2018 and had to wait until the following visit on January 22, 2019. *Id.*; Ex. 2 at 3; Ex. 7 at 2. Otherwise, Dr. Natanzi emphasized the statements in Petitioner's affidavits, which reflected immediate pain that later worsened—consistent with SIRVA. Natanzi First Rep. at 6, 9.

Second Report

Dr. Natanzi's Second Report focused on two topics: whether calcific tendinopathy explained Petitioner's injury, and then the temporal relationship of symptoms with vaccination. Natanzi Second Rep. at 1.

Dr. Natanzi defined calcific tendinopathy to be the build-up of calcium in the tendons, which usually occurs because of repetitive use or microtrauma associated with a person's day-to-day activity over the course of a lifetime. Natanzi Second Rep. at 1; M. ElShewy, *Calcific Tendinitis of the Rotator Cuff*, 7 World J. Orthopedics 55, 55 (2016), filed as Ex. 12 (ECF No. 33-2) ("ElShewy"). This type of calcification is usually asymptomatic. Natanzi Second Rep. at 1; ElShewy at 55. Calcification can also be caused by a sudden, more robust injury to a tendon. In theory, this could happen due to vaccine needle overpenetration causing a rotator cuff injury. Natanzi Second Rep. at 1. Taking into account Petitioner's age, Dr. Natanzi opined that the calcific tendinopathy seen on Petitioner's X-ray was consistent with an age-related condition that was likely asymptomatic, both pre- and post-vaccination. *Id*.

SIRVA, on the other hand, is an acute inflammatory process brought on by vaccine interaction with naturally-occurring antibodies, resulting in an exaggerated, robust, and prolonged inflammatory response. Natanzi Second Rep. at 1; Section 14(c)(10). This in turn leads to inflammation of the rotator cuff tendons and/or bursa, which causes pain, limitation in motion, and dysfunction. Natanzi Second Rep. at 1; Section 14(c)(10). Such an acute process was consistent with Petitioner's presentation. Natanzi Second Rep. at 1.

Dr. Natanzi next revisited the temporal relationship between the flu vaccine and Petitioner's injury (although it was a subject already ruled upon by the Finding of Fact). He again attempted to argue that the totality of the evidence—Petitioner's affidavit and statements in medical records several months post-vaccination—confirmed a one-day onset. Natanzi Second Rep. at 2; Ex. 3 at 93. He also repeated his contention that delay in treatment of SIRVA is common. Natanzi Second Rep. at 2; M. Bodor & E. Montalvo, *Vaccination-Related Shoulder Dysfunction*, 25 Vaccine 585, 586 (2007), filed as Ex. 9(i) (ECF No. 31-9) (noting how a patient suffered a SIRVA injury but did not seek medical help until two months later); Barnes at 919 (reporting a SIRVA injury in a 22-year-old female who did not initially present to her care provider until two months after vaccination).

However, Dr. Natanzi also opined that even if Petitioner's onset had occurred longer than 48 hours after vaccination (the finding I had made in dismissing the Table claim), a SIRVA injury was still possible. Natanzi Second Rep. at 2. Although SIRVA typically presents within the first few days, there were examples of patients whose symptoms manifested several days later. *See* Atanasoff at 8050 (noting of a series of 13 case studies, one patient presented with symptoms after four days). Given in this case that there is no other explanation for Petitioner's injury pre-

vaccination, SIRVA remained as the most likely classification for the injury, in Dr. Natanzi's view. Natanzi Second Rep. at 2.

B. *Respondent's Expert – Geoffrey D. Abrams, M.D.*

Dr. Abrams, a board-certified orthopedic surgeon, prepared one written report for Respondent, opining therein that Petitioner cannot establish a causation-in-fact claim based on the record. Report, dated August 15, 2022, filed as Ex. A (ECF No. 37-1) ("Abrams Rep.").

Dr. Abrams received a Bachelor of Arts in Human Biology with a concentration in Neuroscience from Stanford University in 2000. *Curriculum Vitae,* filed as Ex. B on August 15, 2022 (ECF No. 37-4) ("Abrams CV") at 1; Abrams Rep. at 1. He received his medical degree from the University of California, San Diego. Abrams CV at 1. He completed a surgical internship at Stanford University in 2008. *Id*. Dr. Abrams completed his residency at Stanford University Hospital and Clinics in 2012, and a fellowship at Rush University Medical Center in 2013. *Id*. Dr. Abrams is board certified in Orthopedic Surgery, with a subspeciality in Orthopedic Sports Medicine. *Id.*; Abrams Rep. at 1. He is licensed to practice medicine in Illinois and California and is a California Fluoroscopy Supervisor and Operator. Abrams CV at 2. He holds academic appointments at the Stanford University School of Medicine and the Veterans Administration Hospital of Palo Alto. *Id.* at 1; Abrams Rep. at 1. He serves as the head team physician for several of Stanford University's varsity teams, and is also an assistant team physician for the San Francisco 49ers. Abrams CV at 23; Abrams Rep. at 1.

Dr. Abrams summarized the pertinent medical facts and only briefly addressed Petitioner's causation theory, purporting that it breaks down in the second and third *Althen* prong—since there is no direct evidence that the vaccine Petitioner received either caused his left shoulder symptoms or was temporally related to them. Abrams Rep. at 2–3.

First, Dr. Abrams opined that Petitioner's shoulder injury was not likely related to his flu vaccine. Abrams Rep. at 3. Rather, two other explanations existed: (1) calcific tendonitis, or (2) an idiopathic manifestation of frozen shoulder. *Id.* at 4. The record provided support for calcific tendonitis as the most likely cause. It was seen on Petitioner's X-rays, and (as Dr. Natanzi admitted) it was age-related, thereby consistent with Petitioner's own age when he received the relevant vaccine. *Id.* at 3–4; Natanzi First Rep. at 7; Natanzi Second Rep. at 1. Petitioner's calcific tendonitis was also likely present *prior* to vaccination. Abrams Rep. at 4. While calcific tendonitis can be asymptomatic, it can also later lead to significant shoulder dysfunction, including suddenly-manifesting pain. *Id.*; A. De Carli et al., *Calcific Tendonitis of the Shoulder*, 2 Joints 130, 131 (2014), filed as Ex. A, Tab 1 (ECF No. 37-2). And Dr. Abrams disputed Dr. Natanzi's contention that there is a connection between SIRVA and calcific tendonitis, maintaining that this is not supported in the literature. Abrams Rep. at 3.

Sudden manifestation of symptoms attributable to an idiopathic occurrence of frozen shoulder could also explain Petitioner's presentation. Frozen shoulder, Dr. Abrams opined, can arise without an identified cause. Abrams Rep. at 4. It is a commonly-diagnosed condition associated with increased age and medical comorbidities, and can be persistent in patients like Mr. Bulman, who (this record reveals) do not obtain physical therapy and/or a cortisone injection as treatment after their symptoms manifest. *Id.*; C. M. Robinson et al., *Frozen Shoulder*, 94 J. Bone & Joint Surgery – British 1, 8 (2012), filed as Ex. B, Tab 2 (ECF No. 37-3) (describing diagnosis of frozen shoulder) ("Robinson"). Petitioner's clinical symptoms of pain and decreased motion also matched the clinical picture of frozen shoulder. Abrams Rep. at 3–4; Ex. 3 at 12, 95–96. In fact, Dr. Abrams proposed that calcific tendonitis *itself* could causally explain frozen shoulder. Abrams Rep. at 4; Robinson at 1–2.

Second, Dr. Abrams addressed the issue of onset and its relationship to vaccination. In so doing, he noted that the Finding of Fact had determined that a 48-hour onset from the time of vaccination was not supported by the record. Abrams Rep. at 3. On top of that, Mr. Bulman had not sought medical treatment for his shoulder pain until four months post-vaccination. *Id*. And Dr. Natanzi's explanation for treatment delay (that patients expected their pain to resolve on its own, and thus waited to seek care) was undercut by the fact that Petitioner *had* sought medical care from his PCP on December 26, 2018—three months after the vaccination—but did not at this time report shoulder pain. *Id*. In fact, the record of this visit documented a number of medical problems, suggesting to Dr. Abrams that shoulder pain would have also been mentioned at this time had it been a concern, and thus that the failure to mention pain by this time was meaningful. *Id*. Dr. Abrams also disputed Dr. Natanzi's contention that SIRVA could occur even if onset exceeded vaccination by more than two days, maintaining that a very close-in-time onset is a central and defining characteristic of SIRVA. *Id.* at 4.

III. Procedural History

After the case's initiation in the summer of 2019, it was assigned to SPU, since it asserts a SIRVA claim—a kind of vaccine injury that routinely results in settlement or other prompt resolution. However, Respondent filed a status report indicating that he intended to contest entitlement, and subsequently filed his Rule 4(c) Report explaining there was not a preponderance of evidence demonstrating the requisite facts necessary to establish a Table SIRVA injury (particularly as it relates to a 48-hour onset). ECF No. 20. I provided the parties with the opportunity to file any additional evidence or memoranda relevant to onset, and ultimately dismissed the Table claim for failure to meet that element. ECF No 26. After the case was transferred from SPU, I set deadlines for expert reports ,and eventually a scheduling order for briefing on entitlement. The matter is now ripe for resolution.

IV. Parties' Arguments

Petitioner argues that he was correctly diagnosed with a SIRVA injury. Mot. at 16.[4] He further maintains that he has met the causation-in-fact burden based on the factors established by the Federal Circuit in *Althen v. Sec'y of Health & Hum. Servs*., 418 F.3d 1274 (Fed. Cir. 2005); Reply at 4. Statements from Petitioner's expert, he purports, support the contention that the flu vaccine can cause SIRVA via a prolonged inflammatory response. Mot. at 15–19; Reply at 5–7. And Petitioner proposes that he has demonstrated a logical sequence of cause and effect that the flu vaccine "did cause" his injury. Mot. at 23–24; Reply at 9–10. No other causal agent was documented in the medical records that preceded his vaccination. Mot. at 23–24; Reply at 9. Respondent's expert can only opine on the *possibility* of idiopathic frozen shoulder (without evidentiary basis) or calcific tendinitis (incidental, asymptomatic findings on an MRI). Mot. at 24–25; Reply at 9–10. Finally, the timing of his onset began immediately (within 48 hours)—according to Petitioner's affidavit and medical records (though admittedly, not the visit following vaccination). Mot. 20–22; Reply at 7–9. He states there is no evidence in the record to contradict onset beginning close in time to vaccination. Reply at 9. However, even an onset exceeding 48 hours would be medically acceptable, given the literature and the testimony of Dr. Natanzi. *Id.* at 8–9; Mot. 20–22.

In opposing entitlement, Respondent questions the "existential" basis for the alleged injury, maintaining that SIRVA is defined by administrative rulemaking rather than a recognized medical diagnosis. Opp. at 10–13; *Lasnetski*, 128 Fed. Cl. at 262; *Lombardi*, 656 F.3d at 1352; *Broekelschen*, 618 F.3d at 1349. Additionally, even if Petitioner could prove a medically recognized injury, whether called SIRVA or something else, Petitioner has not preponderantly established a reliable medical theory causally connecting his vaccination to his injury. Opp. at 13–15. Petitioner relies on the theory of an immune-mediated inflammatory response, but the intended purpose in vaccination does not equate to a pathogenic process resulting in injury. *Id.* at 13 n.4. Petitioner also relies on case reports that do not assist in establishing causation. *Id.* at 13–14.

[4] Petitioner also argues that SIRVA is a recognized vaccine injury, maintaining that Respondent erroneously relies on several decisions that discuss the context in which post-vaccination symptoms have not been deemed to constitute an injury. Reply at 2–4; *Lasnetski v. Sec'y of Health & Hum. Servs.*, 128 Fed. Cl. 242 (Fed. Cir. 2017) (finding that petitioner failed to identify the underlying injury and thus determining she was not entitled to compensation); *Lombardi v. Sec'y of Health & Hum. Servs.*, 656 F.3d 1343 (Fed. Cir. 2011) (holding that it was appropriate for the special master to first determine what injury, if any, was supported by the evidence before applying the *Althen* test in the fact of extreme disagreement among experts as to diagnosis); *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339 (Fed. Cir. 2010) (determining that identification of a petitioner's injury is a prerequisite to an *Althen* analysis when there is more than one proposed injury that have significantly different pathologies). However, resolution of the present claim does not turn on whether a non-Table SIRVA is or is not an injury, but rather whether the facts of *this* case undercut the conclusion that Petitioner's at least SIRVA-like presentation could be vaccine-associated—given the non-Table onset plus evidence of other explanations for the injury.

Althen prong two is also unmet, Respondent argues, because Petitioner has failed to establish a logical sequence of cause and effect—noting that a mere proximate temporal relationship between vaccination and injury is not enough. Opp. at 16–19. There are also two viable alternative causes for his shoulder pain evident in the medical record: calcific tendinitis and idiopathic frozen shoulder. *Id.* at 18–19. And Petitioner's showing under *Althen* prong three also fails, since its primary foundation is his repeated assertion (in direct contravention to the Finding of Fact) that his injury occurred within 48 hours of vaccination. *Id.* at 15–16. Indeed, no showing of a medically-acceptable relationship between vaccine and injury is possible, because insufficient support for an onset even a few days after vaccination has been established in this case. *Id.* at 15.

V. Applicable Legal Standards

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[5] My Finding of Fact precludes recovery on the basis of a Table SIRVA claim.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions;

[5] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. App'x. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health and Hum. Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005): "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury."

Each *Althen* prong requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245 ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)).

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*. *See Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) ("[h]owever, in the past we have made clear that simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof." (citing *Moberly*, 592 F.3d at 1322)); *see also Howard v. Sec'y of Health & Hum. Servs*., 2023 WL 4117370, at *4 (Fed. Cl. May 18, 2023) ("[t]he standard has been preponderance for nearly four decades"), *appeal docketed,* No. 23-1816 (Fed. Cir. Apr. 28, 2023). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted);

Tarsell v. United States, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum.*

Servs., 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Legal Standards Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [ ] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially

where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Hum. Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, the Federal Circuit has also noted that there is no formal "presumption" that records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.,* 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral or written testimony (provided in the form of an affidavit or declaration) may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs*., 219 F.3d 1357,

1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). Under *Daubert*, the factors for analyzing the reliability of testimony are:

> (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs*., 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs*., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs*., No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26

("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. *Consideration of Medical Literature*

Both parties filed medical and scientific literature in this case, but not all such items factor into the outcome of this decision. While I have reviewed all the medical literature submitted, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, No. 2015–5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.,* 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

E. *Standards for Ruling on the Record*

I am resolving Petitioner's claim on the filed record, and the parties have not challenged my determination to do so. Mot. at 1; Opp. at 1. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Hum. Servs*., 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Hum. Servs*., No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided case on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Hum. Servs*., 38 Fed. Cl. 397, 402–03 (1997) (determining that special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

I. Interplay Between Table and Non-Table Claims Based on Same Facts

It is not uncommon for the same facts relevant to an alleged vaccine injury to be the basis for both a Table and non-Table claim, such that the latter can viable even if the former is not. Indeed, in the SIRVA context in particular, I routinely find[6] (as here) that a Table element could not be met, but then transfer the case out of SPU for resolution as a non-Table claim. At that point, however, the context for analysis changes substantively. The nature of the specific showing that must be met to obtain entitlement for a non-Table claim is quite different.

Causation is presumed for Table claims—meaning the Government has already made a determination, when announcing the existence of a Table claim, that sufficient scientific and medical evidence exists to allow Program claimants to seek damages without also requiring them to prove, for example, that a particular vaccine "can cause" an injury. In addition, Table claimants need only prove facts sufficient to meet certain elements of the claim at issue. *See* 42 C.F.R. § 100.3(b)(10). Most of the time, this means the petitioner must factually prove that (a) he received a covered vaccine, (b) he suffered a specific injury (consistent with the Table's "qualifications and aids to interpretation," which provide detailed definitions), and (c) the injury occurred in a defined timeframe measured from the time/date of vaccination. *Germaine v. Sec'y of Health & Hum. Servs.*, 155 Fed. Cl. 226, 227 (2021) (discussing the elements needed for compensation of a Table injury compared to those of a non-Table injury); *Spaans v. Sec'y of Dep't of Health & Hum. Servs.*, No. 12-585V, 2012 WL 5928730, at *1 (Fed. Cl. Spec. Mstr. Nov. 6, 2012) (dismissing a claim involving a non-covered vaccine).[7]

The specific Table elements relevant to a defined injury tend to be synergistically related, based on medical science about how (and when) a putative vaccine injury is *most likely* to occur. SIRVA provides an excellent example. SIRVA is believed to occur almost *immediately* after the improper administration of a vaccine. G. Cross et al., *Don't Aim Too High: Avoiding Shoulder Injury Related to Vaccine Administration*, 45 Australian Family Physician 303, 303 (2016), filed as Ex. 9(c) (ECF No. 31-3). Thus, a Table SIRVA is only viable if preponderant evidence exists establishing pain very close in time to vaccination. While more often than not Table claimants allege immediate pain, a Table SIRVA can succeed even if the pain does not manifest until up to 48 hours post-vaccination. The claim's most likely temporal "target" for occurrence has thus been widened somewhat, in fairness to possible claimants. *See, e.g.*, National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 FR 45132-01 ("[i]n order to

[6] The Chief Special Master is responsible for adjudicating all SPU claims.

[7] Sometimes expert input is required to adjudicate Table claims (for example, when a diagnosis is disputed), although it is not common.

capture the broader array of potential injuries, the Secretary proposes to add SIRVA for all tetanus toxoid-containing vaccines that are administered intramuscularly through percutaneous injection into the upper arm. The interval of onset will be less than or equal to 48 hours").

Unsuccessful Table claims are not usually dismissed in their entirety even if it is determined that one or more Table elements cannot be met.[8] Nevertheless, thereafter the "road to entitlement" becomes more difficult (although the preponderant burden of proof is consistent) once the claim becomes subject to the non-Table, causation in fact analysis. Although non-Table claimants may often be able to take advantage of the evidence that resulted in the Table presumption in their effort to satisfy the first, "can cause" *Althen* prong,[9] they cannot rely on how close they came to meeting the Table requirements. *See, e.g.*, *Fantini v. Sec'y of Health & Hum. Servs.*, No. 15-1332V, 2022 WL 1760730, at *22 (Fed. Cl. Spec. Mstr. May 2, 2022) (". . . Program claimants cannot "piggyback" on the Table requirements when attempting to prove a non-Table claim."); *Greene v. Sec'y of Health & Hum. Servs.*, No. 11-631V, 2018 WL 3238611, at *9 (Fed. Cl. Spec. Mstr. May 7, 2018) (noting that an expert's opinion on the timing issue of a brachial neuritis claim relied on conclusory determinations that the "Table time periods were not that far off the time period in question (something Program law says is not permitted)"). Rather, they must support each prong with sufficient preponderant evidence.

II. Petitioner has Not Carried his Burden of Proof

As noted, I have already determined that Table onset could not be met in this case. As a result, I disregard Dr. Natanzi's efforts to vouch for a more immediate onset despite my fact finding. Also important is the fact that I *did not identify a likely onset date for Petitioner's pain.* The January 22nd record actually allowed for the possibility of pain occurring *any time* from after September 27th (more than two days post-vaccination) to sometime in October. Ex. 3 at 93, 95–96.

[8] The failure of a Table claim would usually only produce the case's full dismissal if it was preponderantly established by the record evidence that *no* form of the claim could succeed. For example, flu vaccine/Guillain-Barré syndrome cases cannot succeed as Table claims when onset exceeds 42 days—but a case where onset was extremely long (say, three months) would not likely be entertained as a non-Table claim either, since special masters have almost never found onset to be medically acceptable outside of eight weeks/two months (and even that timeframe is not universally embraced among the special masters). *See, e.g.*, *Chinea v. Sec'y of Health & Human Servs.*, No. 15-095V, 2019 WL 1873322, at *33 (Fed. Cl. Mar. 15, 2019), *mot. for review den'd*, 144 Fed. Cl. 378 (2019) (finding that the onset of the petitioner's GBS occurred eleven to twelve weeks after her vaccination, well beyond the six- to eight-week medically appropriate timeframe for the occurrence of vaccine-induced GBS).

[9] *See L.J. v. Sec'y of Health & Hum. Servs.*, No. 17-0059V, 2021 WL 6845593, at *14 (Fed. Cl. Spec. Mstr. Dec. 2, 2021) ("[s]uch recognition by Respondent of the evidence supporting a causal link between vaccine and injury – since the very decision to add a claim reflects Respondent's determination that valid science supports revising the Table - has been held to support the establishment of the theory required by the first *Althen* prong").

This claim fails primarily on the second and third *Althen* prongs.[10] First, and most significantly, the record does not support the conclusion that Petitioner's onset occurred in medically-acceptable time from vaccination. Even if it is assumed (somewhat reasonably) that vaccines can cause SIRVA, it is far more likely than not that the onset would be close to vaccination. Indeed, the mechanism of the injury almost *presupposes* that, as Dr. Abrams persuasively established. But it cannot be ascertained on this record *when* Petitioner's onset most likely occurred—and even then, Dr. Natanzi has not established that a range of post-vaccination pain onset, occurring any time between more than two days to a week (or more) post-vaccination, would be medically acceptable. The delay in treatment also interfered with a finding on the third prong; even if it is reasonable to expect that sometimes individuals were delay treatment, it can also be evidence of a moderate, tolerable condition, and here that kind of less-acute course suggests a later onset inconsistent with SIRVA.

Program case law recognizes that not all post-vaccination injuries are vaccine-caused simply because vaccination predated them. *See Galindo v. HHS*, No. 16-203V, 2019 WL 2419552, at *20 (Fed. Cl. Spec. Mstr. May 14, 2019) (citing *U.S. Steel Group v. United States*, 96 F. 3d 1352, 1358 (Fed Cir. 1996) ("[b]ut to claim that the temporal link between these events proves that they are casually related is simply to repeat the ancient fallacy: *post hoc ergo propter hoc*"). And I do not find compelling case reports, or instances of longer onset described in literature like Atanasoff, to be reliable proof of a causal association, or to shed light on what timeframe exceeding the Table period would be reasonable.

Second, it has not been preponderantly established that Mr. Bulman's vaccination likely caused his shoulder injury, however defined. In so determining, I do not embrace Respondent's suggestion that SIRVA is solely a creature of administrative creation. It may well in fact be an injury that could in some instances manifest more slowly. But *this* SIRVA claim fell out of the Table—and although the nature of some of Petitioner's symptoms were not inconsistent with a SIRVA (as I alluded to in my Finding of Fact), the evidence adduced herein *since* that time (which included two experts, as discussed above) reveals *other* potential causes for Petitioner's injury that undermine the vaccine's purported role. The calcific tendonitis finding in particular, as endorsed by Dr. Abrams, could explain Petitioner's symptoms directly, or could have produced a frozen shoulder that explains them. These explanations are as consistent with an onset several days after vaccination as the vaccine itself, and could also result in sudden pain manifestation (albeit

[10] Since all three *Althen* prongs must be met, I need not discuss Petitioner's success on the "can cause" prong. I note, however, that the science supporting SIRVA as a cognizable injury is intertwined with the associated pain occurring *very* close in time to vaccination, if not immediately thereafter. A claimant *could* theoretically establish, through citation to literature and other expert inputs, that the process leading to a SIRVA might take longer than what the Table allows—but the case can be decided on the other *Althen* prongs, so I leave determination of that issue to another day.

occurring longer than a few days post-vaccination). In fact, the calcific tendonitis could well have predated vaccination.

In making this determination, I am not finding that an alternative cause *has* been established, to the exclusion of the flu vaccine. I cannot do so on this record, which does not unambiguously point to a clear explanation for the claimant's shoulder pain. But precedent clearly permits me to consider *all* evidence bearing on the "did cause" prong, and this includes evidence about possible confounding factors that undercut the conclusion a vaccine was causal. Indeed, such evidence is relevant to a Table SIRVA. *Lutz v. Sec'y of Health & Hum. Servs.*, No. 20-1553V, 2022 WL 17820779, at *2 (Fed. Cl. Spec. Mstr. Nov. 15, 2022) (*citing* 42 C.F.R. § 100.3(c)(10)(iv) (noting that no other condition or abnormality can be present that would explain the patient's symptoms for a vaccine recipient to be considered to have suffer SIRVA)). Symptoms that would appear to constitute SIRVA become less likely vaccine-related the further onset is separated from vaccination date—as here—and even more so when other possible explanations for the injury are found in the record, but not adequately distinguished.[11]

This is also not a case in which one side's expert possessed superior knowledge of the relevant injury. Both experts were well-qualified to testify, and proved knowledgeable about the topic at issue. However, Dr. Natanzi in this case did a better job of defending SIRVA *as a Table claim* than he did in explaining how a non-Table, SIRVA-like presentation, with an onset exceeding the Table time by a meaningful amount (if not an inordinately lengthy period) could still be a compensable claim. Dr. Abrams more compellingly interpreted the Petitioner's record, and more persuasively explained why a combination of the Petitioner's age and calcific tendonitis findings undercut the determination that his vaccination was causal.

Ultimately, the mix of facts presented by this case (a long delay in reporting pain; no preponderant showing of Table onset; evidence of confounding factors) do not support the claim. This does not mean that *all* non-Table SIRVAs will fail, or should. But a more robust showing must be made than was offered in this case if they are going to succeed. *Compare L.J. v. Sec'y of Health & Hum. Servs.*, No. 17-0059V, 2021 WL 6845593, at *15–17 (Fed. Cl. Spec. Mstr. Dec. 2, 2021) (noting that petitioner provided preponderant evidence to prevail under the *Althen* test).[12]

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[11] I also do not find, however, that this case presents a "*Shyface"* context—in which a vaccine and alternative cause coexist, but where one cause cannot be deemed predominant, but both were likely substantial. *M.R. v. Sec'y of Health & Hum. Servs.*, No. 16-1024V, 2022 WL 16956497 (Fed. Cl. Spec. Mstr. Oct. 3, 2022), *review granted, opinion vacated sub nom. M.R. v. United States*, No. 16-1024V, 2023 WL 4930490 (Fed. Cl. Aug. 2, 2023), *on remand M.R. v. Sec'y of Health & Hum. Servs.*, No. 16-1024V, 2023 WL 4936727, at *28–29 (Fed. Cl. Spec. Mstr. June 30, 2023). First, although vaccines can cause SIRVAs as defined by the Table, it is not established that they do so when onset occurs more than two days post-vaccination. Second, I cannot on this record find that *any* causal explanation exists for Petitioner's injury, however defined.

[12] Although *L.J.* stands as an example of a successful non-Table SIRVA claim, the facts and circumstances posed therein are distinguishable (and highlight why the present case could not similarly succeed). For starters, the *L.J.* Petition was filed *prior* to the time when SIRVA was added to the Vaccine Table (although I looked to the Table

CONCLUSION

Based on the entire record in this case, I find that Petitioner has not carried his burden of proof. In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with the terms of this Decision.[13]

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

elements for guidance). *L.J.*, 2021 WL 6845593, at *8. In addition, it was undisputed in *L.J.* that the claimant satisfied the first two QAI Table criteria—and thus was able to establish 48-hour onset, unlike in this case. *Id.* at *15, 17. Otherwise, *L.J.* turned on different fact questions involving pain experienced elsewhere in the body.

[13] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.